

### **REMARKS**

Applicants have carefully reviewed the Office Action mailed May 28, 2004, prior to submitting this response. Claims 1-15, 17-22, 24-42, 44-48, 50-56, 58, 59, and 61-63 are pending in the application, wherein, claims 1-15, 17-22, 24-42, 44-48, 50, 53-56, 58, 59 and 61-63 stand rejected and claims 51 and 52 are objected to.

### **Objections**

The drawings are objected to under 35 U.S.C. §132 because they introduce new matter into the disclosure. Specifically, Figure 5 is objected to as showing new matter of a braid (210) that is spaced free from the inner and outer liners, and Figure 6 is objected to as showing new matter of a coil (216) that is established in contact with an inner liner, but free from the outer liner. Applicants respectfully traverse this objection. Applicants assert that no new matter has been added in the drawings and all figures find support in the disclosure as originally filed. In establishing a disclosure, an applicant may rely on the specification, drawings or the original claims as filed. M.P.E.P. §608.04. The specification, as originally filed, stated,

The proximal segment 124 may also comprise a stiffener interposed between an inner liner and an outer cover. The inner liner and outer cover may comprise the materials specified herein for the inner liner 126 and outer cover 130 of the distal segment 122. The outer cover and inner liner of the proximal section may be formed from the same material as the outer cover and inner liner of the distal section, or from different materials. The stiffener may be a knit, braided or coil member comprising a metal alloy such as nitinol or stainless steel, or a polymeric material. The knit stiffener from the distal section may extend into the proximal section. The braid may be formed from a single wire or multiple wires and may comprise more than one material.

Specification page 10, lines 1-10.

Applicants respectfully assert that the specification, as originally filed, sufficiently supports Figures 5 and 6. Figure 5 shows a proximal segment 106 including stiffener comprising a braid 210 interposed between an inner proximal liner 212 and an outer proximal cover 214. The specification, as originally filed, teaches a proximal segment comprising a stiffener interposed between an inner liner and an outer cover, wherein the stiffener may be a braid. The specification states that the braid may be interposed between an inner liner and an outer cover. Applicants have chosen the term “interposed between” in describing the orientation of the

stiffener. Figure 5 shows a braid interposed between an inner liner and an outer cover. Contrary to the Examiner's assertion, the orientation of the stiffener is not intended to be restricted to a specific embodiment, but may be positioned at any location between an inner liner and an outer cover. Figure 5 is illustrative of one possible orientation in view of the specification.

Figure 6 shows a proximal segment 106 including stiffener comprising a coil 216 interposed between an inner liner 212 and an outer cover 214. This embodiment is also sufficiently supported by the specification as originally filed. The original specification states that the stiffener may be a coil. As stated above, Applicants have chosen the term "interposed between" in describing the orientation of the stiffener, thus the orientation of the stiffener is not intended to be restricted to a specific embodiment, but may be positioned at any location between an inner liner and an outer cover. Figure 6 is illustrative of one possible orientation in view of the specification.

Applicants respectfully assert that no new matter has been added to the disclosure with the addition of Figures 5 and 6 and the accompanying description in the specification. Withdrawal of this objection is respectfully anticipated.

Claims 1-15, 17-22, 24-42, 44-56, 58, 59 and 61-63 are objected to because the claims do not clearly recite what Applicant views as their invention. The Examiner requests that if Applicants define "generally not radially expandable" as described in the specification, they are requested to include the phrase "does not increase in diameter more than about 5% when an outwardly directed radial force is applied to an inner surface of the knit member." "When a term of degree is presented in a claim, first a determination is to be made as to whether the specification provides some standard for measuring that degree." M.P.E.P. §2173.05(b). In the current application, the specification provides a sufficient standard for measuring that degree. See specification at page 8, line 18. Applicants respectfully note that M.P.E.P §2173.02 states that the Examiner "should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire." Claims should not be rejected or amendments suggested if Applicant satisfies the statutory requirement with other modes of expression. Definiteness of

claim language must be analyzed in light of the content of the application disclosure. M.P.E.P. §2173.02. Therefore, Applicants respectfully assert no amendment is necessary.

### **Rejections under 35 U.S.C. §102**

Claims 1, 2, 13, 19, 20, 24, 27, 31, 40, 46, 47, 50, 53-56, 58 and 59 stand rejected under 35 U.S.C. §102(b) as being anticipated by JP 05-220225 in view of Samson (U.S. Patent No. 5,702,373). The Examiner asserts JP 05-220225 shows a knitted reinforcing metal member 35 with an inner liner and outer cover, wherein Samson is relied upon for description of the JP 05-220225 document. Applicants respectfully traverse this rejection. "For anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly." M.P.E.P. § 706.02. Applicants respectfully assert that JP 05-220225 fails to teach each and every element of the claimed invention. Therefore, an anticipatory rejection is improper. Although the English language Abstract of JP 05-220225 uses the term "knitted", Applicants assert that JP 05-220225 fails to teach a knitted member as claimed in the current application. Additionally, it appears as if the Examiner is relying on JP 05-220225 as teaching a knit member, while disregarding the remainder of the elements claimed in the present invention. For example, the Examiner has failed to identify where JP 05-220225 teaches a member formed from a plurality of interlocking up loops and down loops or a knit member generally not radially expandable. Applicants respectfully request that the Examiner sufficiently identify the portion of the JP 05-220225 document that teaches at least these elements if he intends to retain the rejection. See M.P.E.P. §707.07(f).

Independent claims 1, 24 and 31 recite a knit tubular member formed from a plurality of interlocking up and down loops that is generally not radially expandable. JP 05-220225 fails to teach either of these aspects of the invention. The figures, especially Figures 5A and 7A, show the wires in a woven or crisscross pattern. The figures in JP 05-220225 clearly do not show interlocking up and down loops, as is recited in the instant claims. The figures in JP 05-220225 show a braided or woven member wherein the wires are wrapped in a helical fashion, whereby there are no interlocking up and down loops present. Thus, when the figures of the Japanese abstract are viewed in light of the accompanying description, it is clear that the term "knit" as used in the document is a surrogate for meaning that the wire is actually woven or braided.

There is no teaching or suggestion in the Japanese patent of a knit tubular member formed from a plurality of interlocking up and down loops, where the knit is generally not radially expandable, as is instantly claimed.

Additionally, JP 05-220225 does not teach a tubular member formed of a plurality of interlocking loops that is generally not radially expandable, as is also recited in the claims. To the contrary, one of skill in the art, upon reviewing the English abstract and figures, would likely conclude the reinforcing layer 35 was radially expandable in order to achieve the transition from the area of tightly woven wires 35A to loosely woven wires 35B. The Examiner has not indicated what language in the English abstract or which figure is being relied on for a teaching of the wire mesh not being radially expandable.

In the Advisory Action mailed April 2, 2004, the Examiner stated that a knitted layer is generally not radially expandable because the loops do not allow the knit free expansion. However, no reference or other support for this assertion was provided at that time or subsequently. If this argument is maintained, Applicants respectfully request the Examiner provide a reference or other teaching to support this assertion. See M.P.E.P. §707.07(f).

As the English language Abstract of JP 05-220225 does not teach a non-radially expandable tubular member made of interlocking up and down loops, it fails to teach every element of the invention as claimed in independent claims 1, 24 and 31. Applicants firmly believe claims 1, 24, 31 and 54-56 are in condition for allowance. Claims 2, 13, 19 and 20 depend from claim 1 and contain significant additional elements; claim 27 depends from claim 24 and contains significant additional elements; and claims 40, 46, 47, 50, 53-56, 58 and 59 depend from claim 31 and contain significant additional elements. Applicants firmly believe that these claims also are in condition for allowance for at least the reasons stated above.

Claims 1-5, 13, 14, 18-20, 24-27, 31-33, 40, 41, 45-47, 50, 53-56, 58 and 59 stand rejected under 35 U.S.C. §102(e) as being anticipated by Leoni (U.S. Patent No. 5,772,681). The Examiner asserts that Leoni describes a catheter having a knitted reinforcing member of nitinol between an inner liner and outer cover that is generally not expandable in the section adjacent to the balloon section. Applicants respectfully traverse this rejection.

Leoni teaches a dilation catheter having an expandable balloon section. The balloon section has a reinforcement net preventing over-expansion of the balloon. The reinforcement net

is made of metallic monofilaments extending helically around the longitudinal axis of the balloon section and moveable with respect to each other at the crossover points to allow expansion of the balloon section. Applicants respectfully assert that Leoni fails to teach that which is claimed in the current invention. Namely, Leoni fails to teach a knit tubular member formed from a plurality of interlocking up loops and down loops that is generally not radially expandable.

Although Leoni teaches a reinforcing net comprising metallic monofilaments that may be helically wound, braided, or knitted, Leoni's teachings must be read in light of the specification. As discussed in an early response, the Meriam-Webster Online Dictionary (obtainable at [www.m-w.com](http://www.m-w.com)) contains multiple definitions for the word "knitted." There are at least three plain meanings of "knit" including (1) to tie together; (2) to link firmly or closely; and (3) to form by interlacing yarn or thread in a series of connected loops with needles. Given the different plain meanings possible for "knit", the skilled artisan would logically turn to the remainder of the specification and accompanying figures in the reference in an attempt to determine which meaning of "knit" was intended by the reference. It is apparent from a close examination of Leoni that the definition of "knitted" relied on in Leoni is not the same as is intended in the current application. Leoni teaches a reinforcing net made of metallic monofilaments wherein the contact points of the mesh rows are moveable with respect to each other in the crossover points. See column 3, lines 55-60. The limitation that the reinforcing net includes mesh rows extending helically around the longitudinal axis, wherein the mesh rows are moveable with respect to each other in the crossover points is equally limiting for a knitted reinforcing net as it is for a braided reinforcing net as taught in Leoni. See column 6, lines 16-34. Claim 6 of Leoni states in part, "wherein said reinforcement net (2) is a knitted net of metallic monofilaments, mesh rows of said net extending helically around the longitudinal axis of the middle section...wherein said mesh rows are moveable with respect to each other in the crossover points (5) during expansion of the balloon section." Thus, the definition of "knit" relied on by Leoni is different from the definition intended in the current application. Therefore, Leoni fails to teach what is claimed in the current application, namely, a knit tubular member formed from a plurality of interlocking up loops and down loops, wherein the knit tubular member is generally not radially expandable.

Applicants respectfully assert that claims 1, 24 and 31 contain at least one element not taught in Leoni. Therefore, they are believed to be in condition for allowance. Claims 2-5, 13, 14, 18-20 and 54-56 depend from claim 1 and contain significant additional elements, claims 25-27 depend from claim 24 and contain significant additional elements, and claims 32, 33, 40, 41, 45-47, 50, 53, 58 and 59 depend from claim 31 and contain significant additional elements. Therefore, these claims are also believed to be in condition for allowance.

### **Rejections under 35 U.S.C. §103**

Claims 1, 8-10, 13, 15, 18-21, 31, 36-38, 40, 42, 45-48, 50, 53-56, 58, 59, 61 and 63 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cook (U.S. Patent No. 4,637,396) in view of Cox (U.S. Patent No. 5,257,974). The Examiner asserts that Cook discloses a catheter section having an elongate knit tubular multifilament member 23 made of interlocking up and down loops having an inner liner 22 and outer cover 24 and radiopaque markers, wherein the catheter section is made so that it only expands to a predetermined diameter. The Examiner further asserts that Cox teaches a multi-layered catheter that is made for predetermined expansion of less than 2.7%, thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Cox in the catheter of Cook. Applicants respectfully traverse this rejection.

Applicants respectfully assert that in relying on a reference under 35 U.S.C. §103, the reference must either be in the field of the Applicant's invention or be reasonably pertinent to the particular problem in which the inventor is concerned. M.P.E.P. §2141.01(a). "While Patent Office classification of references and the cross-references in the official search notes are some evidence of 'nonanalogy' or 'analogy' respectively, the court has found 'the similarities and differences in structure and function of the inventions to carry far greater weight.' *In re Ellis*, 476 F.2d 1370, 1372, cited at M.P.E.P. §2141.01(a). Applicants assert that neither the art taught in Cook nor the art taught in Cox are analogous to that of the current invention. Furthermore, the knitted member of the current invention functions much differently from that taught in Cook. The knit member in Cook is designed of elastic filaments to provide expansion and contraction characteristics of the balloon. See column 3, lines 46-48. However, the knit member of the

current invention provides kink resistance and flexibility to a catheter shaft. See specification, page 3, lines 18-29.

Notwithstanding the fact that Cook teaches a significantly different apparatus from the current invention, namely an expandable balloon having a reinforcing layer to prevent overinflation and potential bursting of the balloon, there is no suggestion or motivation to take the expandable knitted member in Cook for use in the knitted reinforcing layer of the catheter of the current invention. Applicants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness using the stated prior art combination. In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation for combining the teachings of the references found in the prior art. M.P.E.P. §706.02(j). Additionally, there is no motivation or suggestion to combine the teachings of Cook with the teachings of Cox. Cook teaches a balloon catheter having a balloon reinforced by a knitted layer comprising elastic and inelastic plies. (Column 3, lines 10-15.) By using elastic plies, the knitted layer is expandable, and the knitted layer is chosen for its expansion and contraction characteristics. (Column 3, lines 45-48.) Cox, on the other hand, teaches an adapter for use with balloons of intravascular balloon catheters. The adapter of Cox may include a support structure comprising reinforcing fibers woven in the shape of a tube. See column 8, lines 31-34. Cox teaches using a noncompliant sleeve to enhance the properties of a balloon. See column 17, lines 30-35. Cook teaches that an expandable balloon having a knitted layer is superior to prior known fabric reinforced balloons because,

Prior known balloons reinforced with a braided or woven fabric tube are unable to expand in diameter without correspondingly decreasing in length. However, a balloon reinforced with the knitted fabric tube described herein is capable of expanding three-dimensionally such that an increase in diameter does not require a decrease in length of the balloon.

Column 3, lines 46-55 (emphasis added).

In other words, Cook actually teaches away from the teachings of Cox. “A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” M.P.E.P. §2141.02 (emphasis in original). Therefore, in view of the fact that Cook actually teaches away from Cox, there is no motivation or suggestion

to combine the teachings of Cook with those of Cox. Applicants assert no *prima facie* case of obvious has been established with this combination.

Applicants respectfully assert that no *prima facie* case of obviousness has been established as to claims 1 and 31 in view of the teachings of Cook and Cox. Therefore, it is requested that this rejection be withdrawn. Claims 1 and 31 are believed to be in condition for allowance. Claims 8-10, 13, 15, 18-21, 54-56 and 61 depend from claim 1 and contain significant additional elements and claims 36-38, 40, 42, 45-48, 50, 53, 58, 59 and 63 depend from claim 31 and contain significant additional elements. Therefore, these claims are also believed to be in condition for allowance.

Claims 2-7, 11, 12, 14, 24-30, 32-35, 39, 41 and 62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cook (U.S. Patent No. 4,637,396) and Cox (U.S. Patent No. 5,257,974) in view of Leoni (U.S. Patent No. 5,772,681). The Examiner asserts that Cook and Cox disclose the claimed invention except for using nitinol as the knitted layer, and Leoni teaches using nitinol as the knitted layer to restrict expansion as a reinforcing layer. The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Leoni with the device of Cook and Cox. Applicants respectfully traverse this rejection. As stated above, a *prima facie* case of obviousness has not been established with respect to the stated combination of prior art references. Applicants respectfully request the rejection be withdrawn and assert that claims 2-7, 11, 12, 14, 24-30, 32-35, 39, 41 and 62 are in condition for allowance.

Claims 6-12, 15, 21, 28-30, 34-39, 42 and 48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05-220225 or Leoni (U.S. Patent No. 5,772,681) and further in view of Andersen et al. (U.S. Patent No. 5,674,276). The Examiner asserts that JP 05-220225 or Leoni disclose the claimed invention except for using multifilaments with first and second materials of a metal and a polymer. The Examiner asserts that Andersen et al. teach using multifilaments with first and second materials of a metal and a polymer, thus it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of JP 05-220225 or Leoni with the teachings of Andersen et al. Applicants respectfully traverse this rejection. As explained above, neither JP 05-220225 nor Leoni teach the claimed invention, and Andersen et al. fail to remedy the shortcomings of JP 05-220225 and Leoni. For the reasons



stated above, Applicants believe the rejection should be withdrawn, asserting that the stated claims are in condition for allowance.

Claims 17, 22, 44 and 48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05-220225 or Leoni (U.S. Patent No. 5,772,681) in view of Jang et al. (U.S. Patent No. 4,898,591). The Examiner asserts that JP 05-220225 or Leoni disclose the claimed invention except for the materials of construction of the inner and outer liner and cover respectively. The Examiner asserts that Jang et al. teach the use of polyethylene as an inner liner and outer cover of a reinforced catheter, and it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Jang in the invention of JP 05-220225 or Leoni. Applicants respectfully traverse this rejection. As explained above, neither JP 05-220225 nor Leoni teach the claimed invention, and Jang et al. fail to remedy the shortcomings of JP 05-220225 and Leoni. For the reasons stated above, Applicants believe the rejection should be withdrawn, asserting that the stated claims are in condition for allowance.

Claims 17, 22, 44 and 48 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cook (U.S. Patent No. 4,637,396) and Cox (U.S. Patent No. 5,257,974), and further in view of Jang et al. (U.S. Patent No. 4,898,591). The Examiner asserts that Cook and Cox disclose the claimed invention except for a polyethylene inner and outer liner and cover. The Examiner asserts that Jang et al. teach the use of polyethylene as an inner liner and outer cover of a reinforced catheter, thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Jang et al. in the invention of Cook and Cox to teach the claimed invention. Applicants respectfully traverse this rejection. As stated above, a *prima facie* case of obviousness has not been established by combining the teachings of Cook and Cox. Jang et al. fail to remedy this shortcoming. Thus no *prima facie* case of obviousness has been established with the combination of references. Applicants respectfully request the rejection be withdrawn and assert that claims 17, 22, 44 and 48 are in condition for allowance.

**Conclusion**

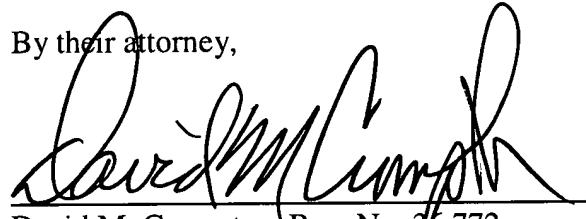
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are currently in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Jill McFadden et al.

By their attorney,

Date: 8/13/04

A handwritten signature in black ink, appearing to read "David M. Crompton", written over a horizontal line.

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